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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/606,302	06/25/2003	Danilo Porro	2027.594096/RFE	4661
23720 7590 10/18/2007 WILLIAMS, MORGAN & AMERSON 10333 RICHMOND, SUITE 1100 HOUSTON, TX 77042			EXAMINER JOIKE, MICHELE K	
			ART UNIT 1636	PAPER NUMBER
			MAIL DATE 10/18/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/606,302

Applicant(s)

PORRO ET AL.

Examiner

Michele K. Joike, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 July 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10, 12-33 and 35 is/are pending in the application.
- 4a) Of the above claim(s) 1-6 and 35 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 7-9 and 15-33 is/are allowed.
- 6) ☒ Claim(s) 10, 12-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Receipt is acknowledged of a reply to the previous Office Action, filed July 27, 2007. Claims 1-10, 12-33 and 35 are pending. Claims 1-6 and 35 are withdrawn; claims 7-10 and 12-33 are examined. Any rejection of record in the previous Office Action, mailed March 21, 2007, that is not addressed in this action has been withdrawn.

Because this Office Action only maintains rejections set forth in the previous Office Action and/or sets forth new rejections that are necessitated by amendment, this Office Action is made FINAL.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 12-14 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is maintained for reasons of record set forth in the prior office action.

Response to Arguments Concerning Claim Rejections – 35 USC § 112 (1)

Applicant's arguments filed July 27, 2007 have been fully considered but they are not persuasive.

The following grounds of traversal are presented:

The terms D-arabinose dehydrogenase (ARA), D-arabino-1,4-lactone oxidase (ALO) and L-gulono-1,4-lactone oxidase each have a plain meaning in a well-known art. Any ARA, ALO or L-gulono-1,4-lactone oxidase, regardless of its amino acid sequence, would be operable in the claimed methods. Claims 12-14 are plainly drawn methods using ARAs, ALOs, or L-gulono-1,4-lactone oxidases, wherein the ARAs, ALOs, or L-gulono-1,4-lactone oxidases have the recited levels of similarity or identity. The Examiner's citation of a guinea pig protein that has 79% amino acid homology to rat L-gulono-1,4-lactone oxidase but does not have L-gulono-1,4-lactone oxidase activity (Detailed Action, p. 9) has no bearing on claims 12-14, which recite a protein that *both* has L-gulono-1,4-lactone oxidase activity *and* 70% identity with SEQ ID NO:9. In addition, the Court in *Capon v. Eshhar* addressed what is needed to support generic claims and held "It is not necessary that every permutation within a generally operable invention be effective in order for an inventor to obtain a generic claim, provided that the effect is sufficiently demonstrated to characterize a generic invention" (at 1085). Applicants discuss the generation of recombinant yeast at p. 11, line 26 to p. 17, line 2, and provide specific examples of coding region amplification, transformation into yeast, ascorbic acid production, and assay of same, at p. 23, line 30 to p. 31, line 5.

Applicants' arguments have not been found persuasive for the following reasons.

It does not appear that all of the enzymes are well-known in the art. Thus, it is impossible for one to extrapolate from the nucleic acids and amino acid sequences described herein those sequences that would necessarily meet the structural/functional characteristics of the rejected claims. The prior art does not appear to offset the deficiencies of the instant specification in that it does not describe a set of ALO, ARA or L-gulonono-1,4-lactone oxidase enzymes with even 95% or 98% similarity or identity. As mentioned previously, an article published after the effective filing date of the instant application describes ALOs only from two species: *S. cerevisiae* and *Candida albicans* (Sauer M. et al. *Applied and Environmental Microbiology* 70(10):6086-6091, 2004; cited previously). Huh et al further teach that the ALO enzyme from *S. cerevisiae* has an FAD binding domain at amino acid residues 23-56 and a transmembrane domain between at residues 172-188 (see page 897, 1st column, 1st and 2nd full paragraphs). Otherwise, no other domains, motifs or sequences responsible for ALO specific function were known at the time of Applicant's filing. Therefore, it is unclear how one skilled in the art could know what regions to alter or delete in order to produce an enzyme with 70% identity that maintains the same function. Furthermore, the Examiner was using Nishikimi et al as an example of that. They teach a protein with 79% amino acid homology (see page 21971, 1st column, 1st full paragraph) to L-gulonono-1,4-lactone oxidase, but that does not have the same function. Therefore, not having any guidance as to which regions could or could not be altered in the ALO, ARA or L-gulonono-1,4-lactone oxidase enzymes, it is conceivable that one could alter the L-gulonono-1,4-lactone oxidase to only 79% identity and produce the guinea pig protein of Nishikimi et

al. The specification is not descriptive enough of the motifs or domains or regions that affect function of ALO, ARA or L-gulonono-1,4-lactone oxidase.

Claim 10 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This rejection is maintained for reasons of record set forth in the Office action mailed 8/22/2006.

Response to Arguments Concerning Claim Rejections – 35 USC § 112 (1)

The declaration under 37 CFR 1.132 filed July 27, 2007 is insufficient to overcome the rejection of claim 10 based upon insufficiency of disclosure under 35 U.S.C. 112, first paragraph as set forth in the last Office action because: showing is not commensurate in scope with the claims. Applicants filed a declaration regarding the deposit of strains NRRL Y-30320, NRRL Y-30321, NRRL Y-30322, NRRL Y-30323, NRRL Y-30324, NRRL Y-30325, NRRL Y-30326, NRRL Y-30327, NRRL Y-30328, NRRL Y-30329, NRRL Y-30491, and NRRL Y-30493. However, the specification has been amended to provide the statement that yeast strains have been deposited to the ATCC. There is no mention in the specification or the declaration about which strains have been deposited at ATCC, the date of the deposit, or the address of the depository. ATCC is a different depository than the Agricultural Research Service Culture

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Collection, and the information regarding the requirements for deposit as specified in prior applications must be given regarding the strains deposited at ATCC, not the Agricultural Research Service Culture Collection.

Allowable Subject Matter

Claims 7-9 and 15-33 are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele K. Joike, Ph.D. whose telephone number is 571-272-5915. The examiner can normally be reached on M-F, 9:00-6:30.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Michele K Joike, Ph.D.
Examiner
Art Unit 1636


NANCY VOGEL
PRIMARY EXAMINER